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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/884,260 | 06/19/2001 | Alan Brash | 06027.0002U2 | 3583 |
| 23859 | 7590 | 01/26/2005 | EXAMINER | |
| NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915 | | | NASHED, NASHAAT T | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1652 | |

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/884,260

Applicant(s)

BRASH ET AL.

Examiner

Nashaat T. Nashed, Ph. D.

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-- The MAILING DATE of this communication appears on th cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-23, 26-28, 31-35, 38-40 and 43 is/are rejected.
- 7) ☒ Claim(s) 24, 25, 29, 30, 36, 37, 41 and 42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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The application has been amended as requested in the communication filed November 20, 2004. Accordingly, claims 20, 21, 25 and 30 have been amended, and new claims 32-43 have been entered.

Claims 20-43 are pending and under consideration.

Since a method utilizing the lyase of amino acid sequence of SEQ ID NO: 7 and that utilizing SEQ ID NO: 15 are independent methods and require separate searches in the patent and none patent literature, the two methods are restrictable from one another. Thus, the embodiment of a method utilizing SEQ ID NO: 15 will not be examined in this Office action.

Claims 25, 30, 37 and 42 are object to because they contain non-elected subject matter. The two claims will be examined only to the extent required for the examination of SEQ ID NO: 7.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-24, 27-29, 32-35, 39, and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the prior Office action mailed August 6, 2004.

Applicants argue that they have disclosed two species of the enzyme and their variants and one of ordinary skill in the art would know how to make all possible variants of SEQ ID NO: 7 and SEQ ID NO: 15. Also, they argue that the structure of a biological molecule is not required to satisfy the written description.

Applicants' arguments filed 11/20/04 have been fully considered, but they are found unpersuasive. The claimed method is not limited to the use of variants of SEQ ID NO: 7. It is directed to the use of any fatty acid hydroperoxide lyase from any biological source and its variant having particular kinetic properties. The specification, however, teach said lyase from *Cucumis melo* having the amino acid sequence of SEQ ID NO: 7 and the cited kinetic properties in the claims. The specification has failed to identify any other hydroperoxide lyase from any other biological source having the particular kinetic properties, or how to identify variants of SEQ ID NO: 7 having the particular kinetic

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properties. No teaching in the specification on how to take for example the known hydroperoxide lyase from cucumber or banana, and alter their kinetic properties to those cited in the claims. While mutation methods are known in the prior art and one of ordinary skill in the art are capable of making any mutants of any known hydroperoxide lyase, the specification has failed to identify all possible organisms which provide said lyase with the desired kinetic properties, or to teach one of ordinary skill in the art a method of redesigning any hydroperoxide lyase to a lyase having the particular kinetic properties in the claims. The amendment of the claims to include a structural feature or limiting the claims to a lyase from *Cucumis melo* would vacate these rejections. New claims 32-35, 39, and 40 are included with these rejections for the same reasons set forth in the prior Office action mailed August 6, 2004.

Claims 20-24, 26-29, 31-36, 38-40, and 43 are rejected under 35 U.S.C. 112, first paragraph, for lack of enablement for the reasons set forth in the prior Office action, mailed August 6, 2004.

Applicants argue that they are the first to discover a hydroperoxide lyase with the kinetic properties cited in the claims which has been acknowledged by the patent Office by issuing U. S. patent 6,271,018 ('018), and that enablement requires that the specification describes how to make and use the invention.

Applicants' arguments filed 11/20/04 have been fully considered, but they are found unpersuasive. The examiner agrees with applicants' allegation that they are the first to discover a hydroperoxide lyase from *Cucumis melo* having the amino acid sequence of SEQ ID NO: 7 and the particular relative kinetic parameters cited in the claims. The claims in '018 patent are limited to those nucleic acid sequences encoding a lyase having a specific relative kinetic parameters from *Cucumis melo*. Amending the claims to be limited to said lyase to that from *Cucumis melo* would obviate these rejection. The specification does not provide sufficient guidance to one of ordinary skill in the art commensurate in scope to the claimed invention. The claims are directed to a method of using a hydroperoxide lyase from any source having specific relative kinetic parameters. As indicated in prior Office action, the application teach a method of obtaining the hydroperoxide lyase from *Cucumis melo* of SEQ ID NO: 7 having a particular kinetic properties, but it does not teach such a lyase from any biological or man-made source. New claims 32-35, 39, and 40 are included with these rejections because they have the same scope as the originally rejected claims

Allowable subject matter:

Claims 24, 29, 36, and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Claims 25, 30, 37, and 42 are objected to for containing non-elected subject matter of SEQ ID NO: 15, and as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner
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